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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/920,860

08/03/2001

Daniel E. Alesi

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6633

21395 7590 07/06/2007

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EXAMINER

GRAY, PHILLIP A

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

07/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/920,860		ALESI ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Phillip Gray		3767	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-12, 14-20 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-12, 14-20 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

This non final office action is in response to applicant's communication of 6/15/2004. New art has been found and is applied to this application, see below. Currently claims 1-3,5-12,14-20 and 22-26 are pending and are rejected below.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2,5-8, 10-11,14-15, 17-19, 22-23, and 25-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Newby et al. (U.S. Patent 6,298,541). Newby teaches and discloses a safety shield assembly (as in figures 1-16) with a holder (unnumbered, shown in figure 10 and 13), with an extension (as in figure 13, holder end which needle hub extend into) and a sleeve (92), a double ended needle (44) with base (60) with one end extending into the holder and another extending out of the holder (figure 13), a mounted collar (90, 114 or 118) a housing (140, or 163) extending from the rotatable collar, a sheath (50) that matingly fit to said sleeve to establish an environment sealed against bacteria intrusion for the needle end (figures 7-9). Further it is examiners position that the open end of the sheath is sealed and effects a tortuous path with the sleeve to prevent contamination with bacteria or other intrusion (columns 1-3). The Newby sleeve has a semi closed end (end towards holder, fig 13) and the sleeve is sealingly fitting onto the extension whe the needle base is mated to the extension. Further the Housing has "integral locking means" (167), and a housing "locking portion" (194), which coacts with collar "locking portion" (118), see figure 15. Further Newby discloses a cover sealing the other end (see unnumbered piece in figure 11 or element 48)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newby et al. Newby discloses the claimed invention except for forming the sleeve integral with the extension, or neck. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the sleeve integral with the extension, or neck, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893), and it has been held to be within the general skill of a worker in the art to make plural parts unitary as a matter of

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engineering design choice. *In re Larson*, 144 USPQ 347 (CCPA 1965); *In re Lockart* 90 USPQ 214 (CCPA 1951).

Claims 9, 16, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newby et al. in view of Imbert (U.S. Patent 6,027,482). Newby discloses the claimed invention except for the tamper evident seal on said sheath and sleeve. Imbert teaches that it is known to use a tamper evident seal on said sheath and sleeve as set forth in paragraphs at column 6 lines 51-58 and figure 8 to provide evidence as to whether or not the medical device has been tampered or misused and to maintain a sterile device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the safety shield assembly as taught by Newby with a tamper evident seal on said sheath and sleeve as taught by Imbert, since such a modification would provide the safety shield assembly with a tamper evident seal on said sheath and sleeve for providing evidence as to whether or not the medical device has been tampered or misused and to maintain a sterile device.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



PAG

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

